Initial Approval: July 11, 2018

CRITERIA FOR PRIOR AUTHORIZATION

Chemotherapy Agents

PROVIDER GROUP Pharmacy
Professional

MANUAL GUIDELINES All dosage forms of the medications listed in table 1 and table 2 below will require prior authorization.

CRITERIA FOR INITIAL APPROVAL FOR ALL PRODUCTS (MUST MEET ALL OF THE FOLLOWING):

- Medication requested must be prescribed for an FDA-approved indication and use.
- If specified in the indication section of table 1 or table 2, the patient's diagnosis must be confirmed by an FDA-approved genetic or confirmatory diagnostic test prior to approval. If the indication section does not specify that the diagnosis must be confirmed by a specific test, the prescriber must attest that the patient's diagnosis is appropriate for treatment with the medication requested.
- Medication must be prescribed within an FDA-approved age range.
- For medications listed in table 1, dose and frequency of medication requested must be consistent with FDA-approved labeling.
- For medications listed in table 2, prescriber must attest that the medication requested will be used at a dose and frequency consistent with FDA-approved labeling.
- Medication must be used in combination with other chemotherapeutic or adjuvant agents according to the FDA-approved prescribing information, as defined in table 1 and table 2.
- If the medication requested is not indicated for first line therapy, as defined in table 1 or table 2, the trial/failure of previous therapies must be documented prior to approval of the requested medication.
- Medication must be prescribed by or in consultation with an oncologist or hematologist.
- If the medication requested carries a risk of embryo-fetal toxicity per FDA-approved prescribing information, the patient must not be pregnant prior to initiation of therapy and must not become pregnant during treatment. Pregnancy status must be confirmed by a negative pregnancy test. Prescriber must attest that appropriate counseling on effective methods and timeframes of contraception per FDA-labeling is completed prior to therapy initiation for both male and female patients.
- Prescriber must attest that all additional medication-specific safety criteria, as defined in table 1 or table 2, is met.

CRITERIA FOR RENEWAL FOR ALL PRODUCTS:

- Prescriber must attest that the patient has experienced a positive clinical response from continuous treatment with the requested medication and is able to tolerate therapy.
- Prescriber must attest that all additional medication-specific safety criteria, as defined in table 1 or table 2, is met.

TABLE 1. ORAL CHEMOTHERAPY – MEDICATION-SPECIFIC CRITERIA

(*Please note: FDA-approved age ranges are listed in numbered order corresponding to their applicable FDA-approved indication and use)

MEDICATION	MEDICATION-SPECIFIC CRITERIA	
Afinitor® (everolimus) - **Pharmacy**	Indication/Use	1. Postmenopausal women with advanced hormone receptor-positive, HER2-negative breast cancer in combination with exemestane after failure of treatment with letrozole or anastrozole 2. Adults with progressive neuroendocrine tumors of pancreatic origin (PNET) and adults with progressive, well-differentiated, non-functional neuroendocrine tumors (NET) of gastrointestinal (GI) or lung origin that are unresectable, locally advanced or metastatic 3. Adults with advanced renal cell carcinoma (RCC) after failure of treatment with sunitinib or sorafenib 4. Adults with renal angiomyolipoma and tuberous sclerosis complex (TSC), not requiring immediate surgery 5. Adult and pediatric patients aged 1 year and older with TSC who have sub ependymal giant cell astrocytoma (SEGA) that requires therapeutic intervention but cannot be curatively resected 6. Adjunctive treatment of adult and pediatric patients aged 2 years and older with TSC-associated partial-onset seizures.
	Age (years)	1. ≥ 18 2. ≥ 18 3. ≥ 18 4. ≥ 18 5. ≥ 1 6. ≥ 2
	Quantity Limit	1. 10 mg daily (tablets only) 2. 10 mg daily (tablets only) 3. 10 mg daily (tablets only) 4. 10 mg daily (tablets only) 5. 4.5 mg/m^2 (tablets and disperz) 6. 5 mg/m^2 (tablets and disperz
	Safety Criteria	➢ Patient must not be taking Afinitor tablets and disperz concurrently ➢ Embryo-fetal toxicity – Patient must not be pregnant ➢ Patient must not be breastfeeding
Alunbrig™ (brigatinib) - **Pharmacy**	Indication/Use	Anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) who have progressed on or are intolerant to crizotinib.
	Age (years)	≥ 18
	Quantity Limit	90 mg daily X 7 days, 180 mg daily thereafter (if 90 mg tolerated)
	Safety Criteria	➢ Embryo-fetal toxicity – Patient must not be pregnant ➢ Patient must not be breastfeeding
Braftovi™ (encorafenib) - **Pharmacy**	Indication/Use	Unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test, in combination with binimetinib.
	Age (years)	≥ 18
	Quantity Limit	450 mg daily
	Safety Criteria	➢ Patient must not be on concurrent moderate or strong CYP3A4 inducers ➢ Embryo-fetal toxicity – Patient must not be pregnant ➢ Patient must not be breastfeeding
Cabometyx® (cabozantinib) - **Pharmacy**	Indication/Use	Advanced renal cell carcinoma (RCC).
	Age (years)	≥ 18
	Quantity Limit	80 mg daily
	Safety Criteria	➢ Embryo-fetal toxicity – Patient must not be pregnant ➢ Patient must not be breastfeeding
Calquence® (acalabrutinib) - **Pharmacy**	Indication/Use	Mantle cell lymphoma (MCL) who have received at least one prior therapy
	Age (years)	≥ 18
	Quantity Limit	100 mg twice daily
	Safety Criteria	Patient must not be pregnant
Cotellic® (cobimetinib) - **Pharmacy**	Indication/Use	Unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, in combination with vemurafenib.
	Age (years)	≥ 18
	Quantity Limit	60 mg daily days 1-21 of 28-day cycle
	Safety Criteria	➢ Patient must not be on concurrent moderate or strong CYP3A inducers or inhibitors ➢ Embryo-fetal toxicity – Patient must not be pregnant ➢ Patient must not be breastfeeding

TABLE 1 (CONT.). ORAL CHEMOTHERAPY – MEDICATION-SPECIFIC CRITERIA

MEDICATION	MEDICATION-SPECIFIC CRITERIA	
Farydak® (panobinostat) - **Pharmacy**	Indication/Use	Multiple myeloma, in combination with bortezomib and dexamethasone, in patients who have received at least 2 prior regimens, including bortezomib and an immunomodulatory agent.
	Age (years)	≥ 18
	Quantity Limit	20 mg every other day for 3 doses/week during weeks 1 and 2 of 21-day cycle (6 units/21 days)
	Safety Criteria	➢ Patient must not have severe hepatic impairment ➢ Patient must not have a baseline QTcF greater than or equal to 450 msec ➢ Embryo-fetal toxicity – Patient must not be pregnant
Gilotrif® (afatinib) - **Pharmacy**	Indication/Use	1. Metastatic non-small cell lung cancer (NSCLC) whose tumors have non-resistant epidermal growth factor receptor (EGFR) mutations, OR 2. Metastatic, squamous NSCLC progressing after platinum-based chemotherapy
	Age (years)	≥ 18
	Quantity Limit	40 mg daily
	Safety Criteria	➢ Embryo-fetal toxicity – Patient must not be pregnant ➢ Patient must not be breastfeeding
Ibrance® (palbociclib) - **Pharmacy**	Indication/Use	1. Hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with an aromatase inhibitor as initial endocrine based therapy in postmenopausal women, OR 2. Hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with fulvestrant in women with disease progression following endocrine therapy
	Age (years)	≥ 18
	Quantity Limit	125 mg daily for 21 days of 28-day cycle (21 units/28 days)
	Safety Criteria	➢ Patient must not be on a strong CYP3A4 inducer ➢ Embryo-fetal toxicity – Patient must not be pregnant ➢ Patient must not be breastfeeding
Idhifa® (enasidenib) - **Pharmacy**	Indication/Use	Relapsed or refractory acute myeloid leukemia (AML) with an isocitrate dehydrogenase-2 (IDH2) mutation as detected by an FDA-approved test
	Age (years)	≥ 18
	Quantity Limit	100 mg daily (1 unit/day)
	Safety Criteria	➢ Embryo-fetal toxicity – Patient must not be pregnant ➢ Patient must not be breastfeeding
Imbruvica® (ibrutinib) - **Pharmacy**	Indication/Use	1. Mantle cell lymphoma (MCL) who have received at least one prior therapy 2. Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma(SLL) 3. Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma(SLL) with 17p deletion 4. Waldenström's macroglobulinemia (WM) 5. Marginal zone lymphoma (MZL) who require systemic therapy and have received at least one prior anti-CD20-based therapy 6. Chronic graft versus host disease (cGVHD) after failure of one or more lines of systemic therapy
	Age (years)	≥ 18
	Quantity Limit	1. 560 mg daily 2. 420 mg daily 3. 420 mg daily 4. 420 mg daily 5. 560 mg daily 6. 420 mg daily
	Safety Criteria	➢ Embryo-fetal toxicity – Patient must not be pregnant
Kisqali® (ribociclib) - **Pharmacy**	Indication/Use	Hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer as initial endocrine-based therapy in combination with an aromatase inhibitor in postmenopausal women.
	Age (years)	≥ 18
	Quantity Limit	600 mg daily for 21 days of 28-day cycle
	Safety Criteria	➢ Patient must not be on a strong CYP3A4 inducer or drugs known to prolong QT interval ➢ Patient must have a baseline QTcF value less than 450 msec ➢ Embryo-fetal toxicity – Patient must not be pregnant ➢ Patient must not be breastfeeding

TABLE 1 (CONT.). ORAL CHEMOTHERAPY – MEDICATION-SPECIFIC CRITERIA

MEDICATION	MEDICATION-SPECIFIC CRITERIA	
Kisqali® Femara Co-pack (ribociclib-letrozole) - **Pharmacy**	Indication/Use	Hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer as initial endocrine-based therapy in combination with letrozole (aromatase inhibitor) in postmenopausal women.
	Age (years)	≥ 18
	Quantity Limit	1 pack/28 days (Kisqali: 600 mg daily for 21 days of 28-day cycle; Femara: 2.5 mg daily)
	Safety Criteria	➢ Patient must not be on a strong CYP3A4 inducer or drugs known to prolong QT interval ➢ Patient must have a baseline QTcF value less than 450 msec ➢ Embryo-fetal toxicity – Patient must not be pregnant ➢ Patient must not be breastfeeding
Lynparza® (olaparib) - **Pharmacy**	Indication/Use	1. Maintenance therapy in recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in a complete or partial response to platinum-based chemotherapy 2. Advanced ovarian cancer with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) who have been treated with three or more prior lines of chemotherapy 3. Deleterious or suspected deleterious gBRCAm, human epidermal growth factor receptor 2 (HER2)-negative metastatic breast cancer who have been treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting. Patients with HR-positive breast cancer should have been treated with a prior endocrine therapy or be considered inappropriate for endocrine therapy
	Age (years)	≥ 18
	Quantity Limit	1. 300 mg twice daily (tablets only) 2. 300 mg twice daily (tablets); 400 mg twice daily (capsules) 3. 300 mg twice daily (tablets only)
	Safety Criteria	➢ Embryo-fetal toxicity – Patient must not be pregnant ➢ Patient must not be breastfeeding
Mekinist® (trametinib) - **Pharmacy**	Indication/Use	1. Single agent for unresectable or metastatic melanoma with BRAF V600E or V600K mutations 2. Unresectable or metastatic melanoma with BRAF V600E or V600K mutations, in combination with dabrafenib 3. Adjuvant treatment of melanoma with BRAF V600E or V600K mutations, and involvement of lymph node(s), following complete resection, in combination with dabrafenib 4. Metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation, in combination with dabrafenib 5. Locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and with no satisfactory locoregional treatment options, in combination with dabrafenib
	Age (years)	≥ 18
	Quantity Limit	2 mg daily
	Safety Criteria	➢ Embryo-fetal toxicity – Patient must not be pregnant ➢ Patient must not be breastfeeding
Mektovi® (binimetinib) - **Pharmacy**	Indication/Use	Unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test, in combination with encorafenib.
	Age (years)	≥ 18
	Quantity Limit	45 mg twice daily
	Safety Criteria	➢ Embryo-fetal toxicity – Patient must not be pregnant ➢ Patient must not be breastfeeding
Ninlaro® (ixazomib) - **Pharmacy**	Indication/Use	Multiple myeloma, in combination with lenalidomide and dexamethasone, who have received at least one prior therapy.
	Age (years)	≥ 18
	Quantity Limit	3 units/28 days (1 unit on day 1, 8, 15 of 28-day cycle)
	Safety Criteria	➢ Patient must not be on a strong CYP3A inducer ➢ Embryo-fetal toxicity – Patient must not be pregnant ➢ Patient must not be breastfeeding

TABLE 1 (CONT.). ORAL CHEMOTHERAPY – MEDICATION-SPECIFIC CRITERIA

MEDICATION	MEDICATION-SPECIFIC CRITERIA	
Revlimid® (lenalidomide) - **Pharmacy**	Indication/Use	1. Multiple myeloma (MM), in combination with dexamethasone 2. MM, as maintenance following autologous hematopoietic stem cell transplantation (auto-HSCT) 3. Transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes (MDS) associated with a deletion 5q abnormality with or without additional cytogenetic abnormalities 4. Mantle cell lymphoma (MCL) whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib
	Age (years)	≥ 18
	Quantity Limit	1. 25 mg daily on days 1-21 of 28-day cycle 2. 10 mg daily 3. 10 mg daily 4. 25 mg daily on days 1-21 of 28-day cycle
	Safety Criteria	➢ Prescriber, patient and pharmacy must be enrolled in the REMS program ➢ Embryo-fetal toxicity – Patient must not be pregnant ➢ Patient must not be breastfeeding
Rubraca® (rucaparib) - **Pharmacy**	Indication/Use	1. Deleterious BRCA mutation (germline and/or somatic)-associated epithelial ovarian, fallopian tube, or primary peritoneal cancer who have been treated with two or more chemotherapies 2. Maintenance treatment of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy
	Age (years)	≥ 18
	Quantity Limit	600 mg twice daily
	Safety Criteria	➢ Embryo-fetal toxicity – Patient must not be pregnant ➢ Patient must not be breastfeeding
Rydapt® (midostaurin) - **Pharmacy**	Indication/Use	1. Newly diagnosed acute myeloid leukemia (AML) that is FLT3 mutation-positive as detected by an FDA-approved test, in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation 2. Aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL)
	Age (years)	≥ 18
	Quantity Limit	1. 50 mg twice daily on days 8-21 of induction/consolidation cycles 2. 100 mg twice daily
	Safety Criteria	➢ Embryo-fetal toxicity – Patient must not be pregnant ➢ Patient must not be breastfeeding
Stivarga® (regorafenib) - **Pharmacy**	Indication/Use	1. Metastatic colorectal cancer (CRC) who have been previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if RAS wild-type, an anti-EGFR therapy. 2. Locally advanced, unresectable or metastatic gastrointestinal stromal tumor (GIST) who have been previously treated with imatinib mesylate and sunitinib malate. 3. Hepatocellular carcinoma (HCC) who have been previously treated with sorafenib
	Age (years)	≥ 18
	Quantity Limit	160 mg daily on days 1-21 of 28-day cycle
	Safety Criteria	➢ Must monitor liver function tests prior to initiation of therapy and throughout treatment ➢ Embryo-fetal toxicity – Patient must not be pregnant ➢ Patient must not be breastfeeding
Tafinlar® (dabrafenib) - **Pharmacy**	Indication/Use	1. Single agent for unresectable or metastatic melanoma with BRAF V600E mutation as detected by an FDA-approved test. 2. Unresectable or metastatic melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test, in combination with trametinib 3. Metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation as detected by an FDA-approved test, in combination with trametinib 4. Locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and with no satisfactory locoregional treatment options, in combination with trametinib
	Age (years)	≥ 18
	Quantity Limit	150 mg twice daily
	Safety Criteria	➢ Embryo-fetal toxicity – Patient must not be pregnant ➢ Patient must not be breastfeeding

TABLE 1 (CONT.). ORAL CHEMOTHERAPY – MEDICATION-SPECIFIC CRITERIA

MEDICATION	MEDICATION-SPECIFIC CRITERIA	
Tagrisso® (osimertinib) - **Pharmacy**	Indication/Use	1. Metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small cell lung cancer (NSCLC), as detected by an FDA-approved test, whose disease has progressed on or after EGFR tyrosine-kinase inhibitor (TKI) therapy 2. First-line treatment of metastatic NSCLC whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test
	Age (years)	≥ 18
	Quantity Limit	80 mg daily
	Safety Criteria	➢ Patient must have a baseline ECG and LVEF evaluated at baseline ➢ Embryo-fetal toxicity – Patient must not be pregnant ➢ Patient must not be breastfeeding
Venclexta® (venetoclax) - **Pharmacy**	Indication/Use	Chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), with or without 17p deletion, who have received at least one prior therapy
	Age (years)	≥ 18
	Quantity Limit	400 mg daily
	Safety Criteria	➢ Patient must not be on concurrent strong CYP3A4 inhibitors at initiation or ramp-up phase ➢ Embryo-fetal toxicity – Patient must not be pregnant ➢ Patient must not be breastfeeding
Verzenio™ (abemaciclib) - **Pharmacy**	Indication/Use	1. In combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer 2. In combination with fulvestrant (and a gonadotropin-releasing hormone agonist if pre- or perimenopausal) for the treatment of women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer with disease progression following endocrine therapy 3. As monotherapy for HR-positive, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting
	Age (years)	≥ 18
	Quantity Limit	1. 150 mg twice daily 2. 150 mg twice daily 3. 200 mg twice daily
	Safety Criteria	➢ Embryo-fetal toxicity – Patient must not be pregnant ➢ Patient must not be breastfeeding
Xalkori® (crizotinib) - **Pharmacy**	Indication/Use	Metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK) or ROS1-positive as detected by an FDA-approved test.
	Age (years)	≥ 18
	Quantity Limit	250 mg twice daily
	Safety Criteria	➢ Embryo-fetal toxicity – Patient must not be pregnant ➢ Patient must not be breastfeeding
Zejula® (niraparib) - **Pharmacy**	Indication/Use	Maintenance treatment of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy
	Age (years)	≥ 18
	Quantity Limit	300 mg daily
	Safety Criteria	➢ Medication must be initiated within 8 weeks of the most recent platinum-based chemotherapy ➢ Embryo-fetal toxicity – Patient must not be pregnant ➢ Patient must not be breastfeeding
Zelboraf® (vemurafenib) - **Pharmacy**	Indication/Use	1. Unresectable or metastatic melanoma with BRAF V600E mutation as detected by an FDA-approved test 2. Erdheim-Chester Disease with BRAF V600 mutation as detected by an FDA-approved test
	Age (years)	≥18
	Quantity Limit	960 mg twice daily
	Safety Criteria	➢ Embryo-fetal toxicity – Patient must not be pregnant ➢ Patient must not be breastfeeding

TABLE 1 (CONT.). ORAL CHEMOTHERAPY – MEDICATION-SPECIFIC CRITERIA

MEDICATION	MEDICATION-SPECIFIC CRITERIA	
Zydelig® (idelalisib) - **Pharmacy**	Indication/Use	1. Relapsed chronic lymphocytic leukemia (CLL), in combination with rituximab, in patients for whom rituximab alone would be considered appropriate therapy due to other co-morbidities 2. Relapsed follicular B-cell non-Hodgkin lymphoma (FL) who have received at least two prior systemic therapies 3. Relapsed small lymphocytic lymphoma (SLL) who have received at least two prior systemic therapies.
	Age (years)	≥18
	Quantity Limit	150 mg twice daily
	Safety Criteria	➢ Embryo-fetal toxicity – Patient must not be pregnant ➢ Patient must not be breastfeeding
Zykadia® (certinib) - **Pharmacy**	Indication/Use	Metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test
	Age (years)	≥ 18
	Quantity Limit	450 mg daily
	Safety Criteria	➢ Patient must not be on strong CYP3A4 or P-gp inducer ➢ Embryo-fetal toxicity – Patient must not be pregnant ➢ Patient must not be breastfeeding

TABLE 2. INJECTABLE CHEMOTHERAPY AGENTS – MEDICATION-SPECIFIC CRITERIA

(*Please note: FDA-approved age ranges are listed in numbered order corresponding to their applicable FDA-approved indication and use)

MEDICATION	MEDICATION-SPECIFIC CRITERIA	
Bavencio® (avelumab) - **Professional**	Indication/Use	1. Metastatic Merkel cell carcinoma (MCC) 2. Locally advanced or metastatic urothelial carcinoma (UC) who have disease progression during or following platinum-containing chemotherapy OR have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy
	Age (years)	1. ≥ 12 2. ≥ 18
	Safety Criteria	➢ Premedicate with an antihistamine and acetaminophen prior to the first 4 infusions and subsequent infusions as needed. ➢ Embryo-fetal toxicity – Patient must not be pregnant ➢ Patient must not be breastfeeding
Blincyto® (blinatumomab) - **Professional**	Indication/Use	1. B-cell precursor acute lymphoblastic leukemia (ALL) in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1% (MRD-positive). 2. Relapsed or refractory B-cell precursor acute lymphoblastic leukemia
	Age (years)	N/A
	Safety Criteria	N/A
Darzalex® (daratumumab) - **Professional**	Indication/Use	1. Newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant, in combination with bortezomib, melphalan and prednisone 2. Multiple myeloma who have received at least one prior therapy, in combination with lenalidomide and dexamethasone or bortezomib and dexamethasone 3. Multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor, in combination with pomalidomide and dexamethasone 4. Multiple myeloma who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent, monotherapy
	Age (years)	≥ 18
	Safety Criteria	➢ Must premedicate with a corticosteroid, antipyretic and antihistamine
Empliciti™ (elotuzumab) - **Professional**	Indication/Use	Multiple myeloma, in combination with lenalidomide and dexamethasone, who have received one to three prior therapies
	Age (years)	≥ 18
	Safety Criteria	➢ Embryo-fetal toxicity – Patient must not be pregnant ➢ Patient must not be breastfeeding

TABLE 2 (CONT.). INJECTABLE CHEMOTHERAPY AGENTS – MEDICATION-SPECIFIC CRITERIA

MEDICATION	MEDICATION-SPECIFIC CRITERIA	
Herceptin® (trastuzumab) - **Professional**	Indication/Use	1. Adjuvant treatment of HER2-overexpressing node positive or node negative (ER/PR negative or with one high risk feature (i.e. tumor size > 2 cm, age < 35 years of age, histological and/or nuclear grade 2 or 3) breast cancer as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel OR as part of a treatment regimen with docetaxel and carboplatin OR as a single agent following multi-modality anthracycline based therapy, based on an FDA-approved companion diagnostic test. 2. HER2-overexpressing metastatic breast cancer in combination with paclitaxel (first-line treatment) OR as a single agent in patients who have received one or more chemotherapy regimens for metastatic disease, based on an FDA-approved companion diagnostic test. 3. HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma in combination with cisplatin and capecitabine or 5-fluorouracil in those who have not received prior treatment for metastatic disease, based on an FDA-approved companion diagnostic test.
	Age (years)	≥ 18
	Safety Criteria	➢ Embryo-fetal toxicity – Patient must not be pregnant
Imfinzi® (durvalumab) - **Professional**	Indication/Use	1. Locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy OR have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy 2. Unresectable, stage III non-small cell lung cancer (NSCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy
	Age (years)	≥ 18
	Safety Criteria	➢ Embryo-fetal toxicity – Patient must not be pregnant ➢ Patient must not be breastfeeding
Keytruda® (pembrolizumab) - **Professional**	Indication/Use	1. Unresectable or metastatic melanoma 2. Metastatic non-small cell lung cancer (NSCLC) whose tumors have high PD-L1 expression (Tumor Proportion Score (TPS) ≥ 50%) as determined by an FDA-approved test, with no EGRF or ALK genomic tumor aberrations (single agent, first-line treatment) 3. Metastatic NSCLC whose tumors express PD-L1 (TPS ≥ 1%) as determined by an FDA-approved test, with disease progression on or after platinum-containing chemotherapy (single agent). Patients with EGRA or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving Keytruda. 4. Metastatic non-squamous NSCLC, in combination with pemetrexed and carboplatin (first-line) 5. Recurrent or metastatic head and neck squamous cell cancer (HNSCC) with disease progression on or after platinum-containing chemotherapy 6. Refractory classical Hodgkin Lymphoma (cHL), or who have relapsed after 3 or more prior lines of therapy 7. Refractory primary mediastinal large B-Cell lymphoma (PMBCL), or who have relapsed after 2 or more prior lines of therapy 8. Locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing chemotherapy and whose tumors express PD-L1 [Combined Positive Score (CPS) ≥ 10], or in patients who are not eligible for any platinum-containing chemotherapy regardless of PD-L1 status 9. Locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy 10. Unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options OR colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin and irinotecan 11. Recurrent locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma whose tumors express PD-L1 (Combined Positive Score (CPS) ≥ 1) as determined by an FDA-approved test, with progression on or after two or more prior lines of therapy including fluoropyrimidine- and platinum-containing chemotherapy and if appropriate, HER2/neu-targeted therapy 12. Recurrent or metastatic cervical cancer with disease progression on or after chemotherapy whose tumors express PD-L1 (CPS ≥ 1) as determined by an FDA-approved test
	Age (years)	➢ cHL = ≥ 2 ➢ PMBCL = ≥ 2 ➢ MSI-H cancer = ≥ 2 ➢ All other diagnoses = ≥18
	Safety Criteria	➢ Embryo-fetal toxicity – Patient must not be pregnant ➢ Patient must not be breastfeeding

TABLE 2 (CONT.). INJECTABLE CHEMOTHERAPY AGENTS – MEDICATION-SPECIFIC CRITERIA

MEDICATION	MEDICATION-SPECIFIC CRITERIA	
Kyprolis™ (carfilzomib) - **Professional**	Indication/Use	1. Relapsed or refractory multiple myeloma in combination with dexamethasone or with lenalidomide plus dexamethasone, who have received one to three lines of therapy 2. Relapsed or refractory multiple myeloma as a single agent, who have received one or more lines of therapy.
	Age (years)	≥ 18
	Safety Criteria	➢ Embryo-fetal toxicity – Patient must not be pregnant
Lartruvo™ (olaratumab) - **Professional**	Indication/Use	Soft tissue sarcoma (STS), in combination with doxorubicin for the first 8 cycles, with a histologic subtype for which an anthracycline-containing regimen is appropriate and which is not amenable to curative treatment with radiotherapy or surgery.
	Age (years)	≥ 18
	Safety Criteria	➢ Embryo-fetal toxicity – Patient must not be pregnant ➢ Patient must not be breastfeeding
Onivyde® (irinotecan liposome) - **Professional**	Indication/Use	Metastatic adenocarcinoma of the pancreas in combination with fluorouracil and leucovorin after disease progression following gemcitabine-based therapy.
	Age (years)	≥ 18
	Safety Criteria	➢ Patient must have a baseline bilirubin < 2 mg/dL ➢ Patient must not be on concurrent strong CYP3A inhibitors or inducers ➢ Embryo-fetal toxicity – Patient must not be pregnant ➢ Patient must not be breastfeeding
Opdivo™ (nivolumab) - **Professional**	Indication/Use	1. BRAF V600 wild-type unresectable or metastatic melanoma, as a single agent 2. BRAF V600 mutation-positive unresectable or metastatic melanoma, as a single agent 3. Unresectable or metastatic melanoma, in combination with ipilimumab 4. Melanoma with lymph node involvement or metastatic disease who have undergone complete resection, in the adjuvant setting 5. Metastatic non-small cell lung cancer and progression on or after platinum-based chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving Opdivo 6. Advanced renal cell carcinoma who have received prior antiangiogenic therapy 7. Intermediate or poor risk, previously untreated advanced renal cell carcinoma, in combination with ipilimumab 8. Classical Hodgkin lymphoma that has relapsed or progressed after autologous hematopoietic stem cell transplantation (HSCT) and brentuximab vedotin OR 3 or more lines of systemic therapy that includes autologous HSCT 9. Recurrent or metastatic squamous cell carcinoma of the head and neck with disease progression on or after a platinum-based therapy 10. Locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy OR have disease progression within 12 month of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy 11. Microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan 12. Hepatocellular carcinoma who have been previously treated with sorafenib
	Age (years)	MSI-H cancer = ≥ 12 All other diagnoses = ≥18
	Safety Criteria	➢ Embryo-fetal toxicity – Patient must not be pregnant ➢ Patient must not be breastfeeding
Provenge® (sipuleucel-T) - **Professional**	Indication/Use	Asymptomatic or minimally symptomatic metastatic castrate-resistant (hormone-refractory) prostate cancer
	Age (years)	≥ 18
	Safety Criteria	N/A

TABLE 2 (CONT.). INJECTABLE CHEMOTHERAPY AGENTS – MEDICATION-SPECIFIC CRITERIA

MEDICATION	MEDICATION-SPECIFIC CRITERIA	
Rituxan® (rituximab) - **Professional**	Indication/Use	1. Relapsed or refractory, low grade or follicular, CD20-positive B-cell Non-Hodgkin's Lymphoma (NHL), as a single agent 2. Previously untreated follicular, CD20-positive, B-cell NHL in combination with first line chemotherapy and, in patients achieving a complete or partial response to rituximab in combination with chemotherapy, as single-agent maintenance therapy 3. Non-progressing (including stable disease), low-grade, CD20-positive, B-cell NHL as a single agent after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy 4. Previously untreated diffuse large B-cell, CD20-positive NHL in combination with cyclophosphamide, doxorubicin, vincristine and prednisone (CHOP) or other anthracycline-based chemotherapy regimens 5. Previously untreated and previously treated CD20-positive chronic lymphocytic leukemia (CLL) in combination with fludarabine and cyclophosphamide
	Age (years)	≥ 18
	Safety Criteria	➢ Rituxan monotherapy: Obtain CBC and platelet counts prior to each Rituxan course ➢ Rituxan and chemotherapy: Obtain CBC and platelet counts at least monthly
Rituxan Hycela® (rituximab and hyaluronidase human) - **Professional**	Indication/Use	1. Relapsed or refractory, follicular lymphoma as a single agent 2. Previously untreated follicular lymphoma in combination with first line chemotherapy and, in patients achieving a complete or partial response to rituximab in combination with chemotherapy, as single-agent maintenance therapy 3. Non-progressing (including stable disease), follicular lymphoma as a single agent after first-line cyclophosphamide, vincristine and prednisone (CVP) therapy 4. Previously untreated diffuse large B-cell lymphoma (DLBCL) in combination with cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP) or other anthracycline-based chemotherapy regimens 5. Previously untreated and previously treated chronic lymphocytic leukemia (CLL) in combination with fludarabine and cyclophosphamide (FC)
	Age (years)	≥ 18
	Safety Criteria	➢ Patient must have received at least one full dose of a rituximab product by intravenous infusion prior to initiation of treatment with Rituxan Hycela
Tecentriq® (atezolizumab) - **Professional**	Indication/Use	1. Locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing chemotherapy and whose tumors express PD-L1 (PD-L1 stained tumor-infiltrating immune cells [IC] covering ≥ 5% of the tumor area), as determined by an FDA-approved test, OR are not eligible for any platinum-containing chemotherapy regardless of PD-L1 status, OR have disease progression during or following any platinum-containing chemotherapy, or within 12 months of neoadjuvant or adjuvant chemotherapy 2. Metastatic non-small cell lung cancer who have disease progression during or following platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving Tecentriq.
	Age (years)	≥ 18
	Safety Criteria	➢ Embryo-fetal toxicity – Patient must not be pregnant ➢ Patient must not be breastfeeding
Trelstar® (triptorelin) - **Professional**	Indication/Use	Palliative treatment of advanced prostate cancer
	Age (years)	≥ 18
	Safety Criteria	➢ Patient must not have a known hypersensitivity to triptorelin or other GnRH agonists or GnRH ➢ Must be administered under the supervision of a healthcare provider
Xofigo® (radium Ra 223 dichloride) - **Professional**	Indication/Use	Castration-resistant prostate cancer, symptomatic bone metastases and no known visceral metastatic disease
	Age (years)	≥ 18
	Safety Criteria	N/A

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DRUG UTILIZATION REVIEW COMMITTEE CHAIR

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PHARMACY PROGRAM MANAGER
DIVISION OF HEALTH CARE FINANCE
KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT

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DATE

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DATE